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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/745,095	12/20/2000	Leah E. Appel	PC10818AJTJ	8852

7590 07/02/2002

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EXAMINER
GOLLAMUDI, SHARMILA S

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 07/02/2002 9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/745,095	Applicant(s) APPEL ET AL.	
	Examin r Sharmila S. Gollamudi	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sh t with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 April 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) *1, 3-6, 10-11, 32-43, 46-48, 52-55, 58-62, 82-87, 98-100, 102, 109-117, 123, and 125-129* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2, 7-9, 12-32, 44-45, 49-51, 56-57, 63-81, 88-97,101,103-108, 118-122, 124, and 130-131* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3/8 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Continuation of Disposition of Claims: Claims pending in the application are 2,7-9,12-32,44,45,49-51,56,57,63-81,88-97,101,103-108,118-122,124,130 and 131.

DETAILED ACTION

Status of Application

Applicant's election with traverse of Group II in Paper No. 7 is acknowledged. The traversal is on the ground(s) that the search has the same classification and is not burdensome to the examiner. This is not found persuasive because the inventions have different properties and effects. Although, the inventions are in the same classification, distinct properties in the independent claims, i.e. the use of a solubilizer versus a fluidizing agent require a different search. For example, the fluidizing agent changes the onset of the drug through the mechanization of decreasing the pressure of extruding the drug out of the delivery device, whereas the solubilizer effect the solubility of the drug and its uptake in the body. This is one example of the distinct properties of the inventions, detailed differences among each invention is given in Paper No. 7.

The requirement is still deemed proper and is therefore made FINAL.

Applicant's election of Group II with traverse is acknowledged. Applicant's election of species is acknowledged, however after reconsideration the election requirement of the swelling agent, drug-entraining agent, tableting aid, cellulosic polymer, fluidizing agent, solubilizer, pore former, and concentration-enhancing polymer, is withdrawn. The election of the drug, sildenafil citrate is maintained.

Claims 2, 7-9, 12-32, 44-45, 49-51, 56-57, 63-81, 88-97,101,103-108, 118-122, 124, and 130-131 are included in the prosecution of this application. Claims 1, 3-6, 10-11, 32-43, 46-48, 52-55, 58-62, 82-87, 98-100, 102, 109-117, 123, and 125-129 are withdrawn from consideration since they are drawn to unelected invention and species.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 95-97 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 95, the recitation of "said coating of less than .9 times that of the same coating material in nonporous form" is confusing. Further, clarification is requested. The same is the case with claim 96.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2, 7-9, 12-15, 17,18, 22, 25-26, 44-45, 49-51, 56, 64-74, 79-81, 88-96, 101, 103-108, 118-122, and 124 are rejected under 35 U.S.C. 102(b) as being anticipated by Dong et al (5620705).

Dong et al disclose a progesterone tablet containing sodium croscarmellulose, hydroxypropylmethylcellulose (HPMC), mannitol, and magnesium stearate. The displacement layer contains HPMC, sodium carboxymethylcellulose (CMC), and sodium chloride (solubilizer). (Note example 7). The drug composition contains sodium CMC (concentration enhancer polymer) (Note example 8). The bilayer core of surrounded by

a semi-permeable wall containing cellulose acetate having an acetyl content of 39.8% and PEG, with a delivery port (Note example 11 and 12). Dong also discloses a tablet containing PEO (Note examples 1-3). The release rate of the drug is shown in the figures. The reference teaches compression of the tablet under 2.5 ton which corresponds to the instant core strength.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2, 7-9, 12-32, 44-45, 49-51, 56-57, 63-81, 88-97,101,103-108, 118-122, 124, and 130-131 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dong et al (5620705) by itself or in combination with Stella et al (5874418).

Assuming Dong et al does not anticipate the instant invention because the property of core strength is shown to not correspond to instant claims, Dong is deemed obvious to one of ordinary skill in the art since Dong et al teaches all the claimed features and provides the general guidance of making a drug dosage form. Further, Dong et al teaches the different dissolution rates of the drug using different additives (Note examples and figures). Further, Dong et al teaches tartaric acid in the drug and swelling composition (example 15).

Dong et al does not exemplify tartaric acid. The reference does not teach citric acid or sodium starch glycolate.

Stella et al teach a solid dosage form, the preparation of the dosage form, and the reasons for using additives in the composition. Stella teaches the use of pore forming agents such as citric acid, PEO, PVP, etc. to improve the permeability of the film coating (col. 11, lines 64 to col. 12, lines 21). Stella teaches the use of disintegrates such as starch, sodium starch glycolate, or croscarmellulose, and MC (col. 12, lines 17-18). The reference teaches the use of acidifying agents such as citric acid or an alkalinizing agent to stabilize the composition (col. 19, lines 14-25).

It is deemed obvious to use the appropriate acid or swelling agent depending on the drug used in the composition and the rate of release desired because Dong teaches the use of an acid and swelling agent in the drug composition.

Further, Dong et al and Stella et al both teach solid dosage forms and using additives such as polymers, pore forming agents, etc to control the rate of release of the active agent. Further, Stella et al disclose the motivation of using certain additives and their role in the composition.

Conclusion

Any inquiry concerning this communication from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is (703) 305-2147. The examiner can be normally reached M-F from 7:30 am to 4:15pm.

If attempts to reach the examiner by the telephone are unsuccessful, the examiner's supervisor, Jose Dees, can be reached at (703) 308-4628. The fax number for this organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist, whose telephone number is (703) 308-1235.

SSG

JOSE' G. DEES
SUPERVISORY PATENT EXAMINER
1616